

# Decision Memo for Prothrombin Time (PT) (Addition of ICD-9-CM V58.83, Encounter for therapeutic drug monitoring, as a covered indication) (CAG-00339N)

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## Decision Summary

CMS has determined that ICD-9-CM diagnosis code V58.83, Encounter for therapeutic drug monitoring, flows from the existing narrative for conditions for which a PT test is reasonable and necessary. We shall modify the list of “ICD-9-CM Codes Covered by Medicare Program” in the NCD for Prothrombin Time (PT) by adding V58.83.

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## Decision Memo

**This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, Section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.**

TO: Administrative File: CAG – 00339N Addition of ICD-9-CM V58.83, Encounter for therapeutic drug monitoring, as a covered indication for the Prothrombin Time (PT) National Coverage Determination

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SUBJECT: Addition of ICD-9-CM V58.83, Encounter for therapeutic drug monitoring, as a covered indication for the Prothrombin Time (PT) National Coverage Determination

DATE: October 3, 2006

### ***I. Decision***

CMS has determined that ICD-9-CM diagnosis code V58.83, Encounter for therapeutic drug monitoring, flows from the existing narrative for conditions for which a PT test is reasonable and necessary. We shall modify the list of “ICD-9-CM Codes Covered by Medicare Program” in the NCD for Prothrombin Time (PT) by adding V58.83.

### ***II. Background***

On July 24, 2006, CMS formally accepted a request for consideration to add ICD-9-CM code V58.83 to the covered indication code list for the PT NCD.

### ***III. History of Medicare Coverage***

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM Codes Covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes That Do Not Support Medical Necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

#### ***IV. Timeline of Recent Activities***

On July 24, 2006, CMS opened a coding analysis item regarding the addition of V58.83, Encounter for therapeutic drug monitoring, as a covered indication for the PT National Coverage Determination (NCD). We posted a tracking sheet to the Internet (<http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=192>) and solicited public comment for 30 days on the appropriateness of adding code V58.83 to the list of covered codes for the PTT NCD.

We received two comments during the comment period, which ended August 23, 2006. The commenters are coding professionals. They offered opinions regarding other code issues but did not directly comment on the proposed addition of V58.83 to the PT NCD, so we will not respond to those comments here.

## ***V. General Methodological Principles***

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL).

## ***VI. CMS Analysis***

The "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. The PT NCD narrative includes the following indication:

“A PT may be used to assess patients taking warfarin.”

ICD-9-CM instructs that when using code V58.83, “use additional code for any associated long-term (current) drug use.” ICD-9-CM instructions further state that V58.83 excludes “blood-drug testing for medicolegal reasons.”

We believe that ICD-9-CM code V58.83 flows from the narrative portion of the PT NCD since a provision to assess the effects of a therapeutic drug (warfarin) is listed as an indication. Therefore, we have determined that V58.83 should be included on the list of “ICD-9-CM Codes Covered by Medicare Program” for the PT NCD. Clearly, the coverage of PT testing under this code is only reasonable and necessary when the therapeutic drug being monitored is warfarin. We expect that contractors would deny claims for PT testing under this code for any other drug.

We intend to issue a recurring update to the edit module implementing the NCDs to add ICD-9-CM code V58.83 to the list of the ICD-9-CM codes covered for the PT NCD.

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## Bibliography

Widmann's Clinical Interpretation of Laboratory Tests, Eleventh Edition. Sacher RA, McPherson RA eds. F.A. Davis Company, Philadelphia, 2000.

Laboratory Test Handbook, 3<sup>rd</sup> Edition. Jacobs D, Demott W, Finley P, Horvat R, Kasten B, Tilzer L eds. Lexi-Comp Inc., Ohio, 1994.

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